

REMARKS

Preliminarily, the Applicant thanks the Examiner for the courtesy of a lengthy interview with the Applicant's representative on July 11, 2005. As discussed in that interview, the scope and/or applicability of certain of the rejections between this Office action and the most recent preceding one differed without a clear explanation; for example, the previous Office action identified allowable claims (72-74), while the final one indicated that all claims were rejected. The Applicant has made every effort to fully respond to the latest Office action, which was made final. Accordingly, the Applicant respectfully requests reconsideration in light of the amendments and the comments and evidence offered herewith.

The following comments are numbered to correspond to the points raised in the final Office action mailed on 17 May 2005.

1. Claims 39-78 were pending and were rejected. Amendments dated January 26, 2005 were entered; thus the present list of claims indicates claim amendments made relative to the list of claims presented with the January 26, 2005 response.

Claims 39-53 and 56-79 are now presented for consideration: claims 54-55 have been canceled. Amendments to claims 39, 41, 53, 59 and 62 correct minor grammatical matters. No new matter is added by these amendments. Claims 75, 76 and 78 have been amended to recite specific conditions taken from the specification at page 19 lines 4-20 and page 21, lines 1-3. No new matter is added. Claim 79 is new and claims specific compounds described on pages 58-60; it therefore adds no new matter. Entry of these amendments and reconsideration of the claims in light of the following comments are respectfully requested.

2. Claims 39, 40, 42, 45-6, 49, 60, 63, and 68-71 (or claims 39 and 75-78 according to the previous Office action) were rejected under 35 U.S.C. § 112, second paragraph. The Examiner alleges that the term "including one or more heteroatoms" is indefinite. The Examiner then lists several specific examples that allegedly could be encompassed by the term and says the specification does not provide "antecedent basis or description or enablement" for these. The latter

term seems misplaced in the context of a rejection expressly based on 35 U.S.C. § 112, second paragraph: enablement is a separate issue.

If the basis for the rejection is indefiniteness, the issue is whether the term clearly defines claim scope: if the term itself is clear, it has antecedent basis and description in the specification as filed, because the same term appears in the specification. The Applicant believes the claim language satisfies the correct standard for claim interpretation during examination, which is “the broadest *reasonable* interpretation consistent with the specification.” MPEP 2111, quoting In re Hyatt, 54 USPQ2d 1664, 1557 (Fed. Cir. 2000) (emphasis added, in light of the Examiner’s statement during the telephonic interview that the standard to be applied is the “broadest possible” meaning).

Here is how the phrase is presented at one point in the specification, for example: “The alkyl or substituted alkyl may optionally include one or more heteroatoms which can be O, N or S, preferably N and O.” Specification at page 6, lines 3-4. This clearly demonstrates that the “optionally including” term refers to heteroatoms within the alkyl or aryl group, not ones appended to it as substituents; otherwise, it would be entirely redundant to say “substituted alkyl may optionally include one or more heteroatoms.” Clearly, the only “*reasonable* interpretation consistent with the specification” is that ‘including one or more heteroatoms’ refers to having one or more heteroatoms replacing one or more carbon atoms in the alkyl or aryl group being described. This is similar to use of the term ‘heteroaryl’ to describe such aryl groups, for example: it provides a structural description that encompasses a number of well-defined chemical structures, just as the term heteroaryl does. With that established, the structures of the claimed compounds are clear: the claims may be broad, but breadth is not indefiniteness. MPEP 2173.04, entitled “Breadth Is Not Indefiniteness.”

As evidence that this phrase as presented in the claims would be understood by one of ordinary skill to describe alkyl or aryl groups optionally having a heteroatom in place of a carbon atom of the alkyl or aryl group being described, a declaration by one of the inventors is submitted

with this response under 27 C.F.R. § 1.132. The declaration is evidence that the term has a clear meaning in the context in which it is used in the specification and claims.

Moreover, this exact language was accepted by this Examiner in claims in a related application that matured into U.S. 6,589,954. Thus the Applicant believes this term clearly defines the compounds of the invention by structure, and requests that this rejection be withdrawn.

The Examiner employed the vague term ‘reach through’ scope in rejecting the method of treatment claims that use the term ‘proinflammation response’: the Applicant remains confused by the use of the term ‘reach through’ as a basis for a claim rejection. Indeed, the definition the Examiner relies on for this term (and which the Examiner says “must be complied with”) is taken from a “Trilateral Project” description indicating a need to study an issue. That document is not an authoritative source of U.S. patent law, and cannot provide a proper statutory or judicial basis for a claim rejection.

Rather than further debating the definition of that term, the Applicant has responded to the presumed statutory basis for rejections that must underlie the Examiner’s comments in order to constitute a valid basis for a claim rejection. This rejection was included in the 35 U.S.C. § 112, second paragraph rejections of the Office action. Therefore it is interpreted as an indefiniteness rejection. To eliminate this rejection as it relates to the method of use claims, the Applicant has recited in the claims specific conditions to be treated by the compounds of the invention. Removal of any reference to proinflammatory conditions, which the Examiner alleges to be a basis for ‘reach through scope’, obviates this issue insofar as it is understood. The specific conditions inserted into the claims were taken from the specification at page 2, line 20, which refers to specific conditions described in the Background section; page 2, lines 3-10, where the Background section lists specific conditions related to inflammation; and page 21, lines 1-3, which lists specific conditions associated with cardiac failure. Withdrawal of this rejection is therefore requested.

3. The Examiner rejected claims 39, 40, 42, 45-6, 49, 60 and 75-78 under 35 U.S.C. § 112, first paragraph ‘for reasons of record’, and again refers to ‘reaching through’. The Examiner

says that “neither antecedent basis nor enablement for such ‘claimed’ scope can be supported from the specification.” The rejection also refers to the “diversity and unpredictability of the cytokine function” and again suggests that the compound scope is not clear.

This rejection as described in this office action and the previous one seems to blend indefiniteness and breadth issues. That is inappropriate: if a term is alleged to be unclear, in assessing enablement the Examiner is nevertheless required to interpret the claim before determining if it is enabled. According to MPEP 2164.04:

Before any analysis of enablement can occur, it is necessary for the examiner to construe the claims. For terms that are not well-known in the art, or for terms that could have more than one meaning, it is necessary that the examiner select the definition that he/she intends to use when examining the application, based on his/her understanding of what applicant intends it to mean, and explicitly set forth the meaning of the term and the scope of the claim when writing an Office action. See *Genentech v. Wellcome Foundation*, 29 F.3d 1555, 1563-64, 31 USPQ2d 1161, 1167-68 (Fed. Cir. 1994).

The Examiner has not “explicitly set forth” what interpretation was used to assess enablement. To the extent that this rejection may have been based on the presence of the term ‘proinflammation response’ in the method of use claims, it is overcome by the amendment removing that term from the claims. The declaration regarding the interpretation of the phrase “including one or more heteroatoms” as used in the present application is evidence addressing the assertion that the claim term is unclear. Once that term is recognized as a clear description of certain alkyl and aryl groups, the indefiniteness issues and any potential written description issues are resolved.

In the previous Office action, a *Wands* analysis provided by the Examiner referred to the term ‘optionally including’, and to allegations of ‘unpredictability’ that were not understood by the applicant. In that analysis, the Examiner discussed the nature of the invention primarily with regard to the scope of the compound description, and concluded that “no explicit description can be found as to what the intended chemical structure is for such terms.” This appears to be an assertion of indefiniteness, and is believed to be addressed by the evidence and comments provided above.

Also in that *Wands* analysis, the Examiner described unpredictability by reference to other families of compounds that have other activities, including compounds outside the scope of the claims. The Examiner even referred to “the unpredictability of such compounds,” and referred to references describing the activities of certain compounds. It is unclear how other activities that may or may not be possessed by the compounds of the invention or by similar compounds have any impact on the patentability of the compound claims or of the present method of use claims. The Applicant provided evidence with the previous response that it is not uncommon or unexpected for a single compound to have multiple activities. At most, the Examiner’s evidence demonstrates that other activities may be present in some compounds similar to ones within the claim scope. Such activity is irrelevant to the question of whether undue experimentation would be required to make and use the claimed compounds (note that the compound claims do not require that the compounds be used for any particular purpose) or to treat the recited conditions with one of the claimed compounds.

Also in the *Wands* analysis, the Examiner stated that no examples having X¹ as sulfonyl (note: the definition for X¹ does not include sulfonyl) or R⁴ as ‘aryl including heteroatoms’ were provided. The Examiner concluded the *Wands* analysis by saying, “In view of the diversity of utility based on the bicyclic core with distinct substitution as evidenced supra, the lacking of variation for the Markush scope with such breadth finds the claimed scope lacks description as well as enablement.”

The allegations of ‘unpredictability’ related primarily to the description of the use or activity of the compounds, and are believed to be addressed by the amendment that names specific conditions to be treated with the compounds of the invention and eliminates the term ‘proinflammatory response’. The current amendment is thus believed to remove any issues attributable to the asserted “diversity and unpredictability of the cytokine function”, which is presumed to be the antecedent for the ‘diversity of utility’ phrase in the Examiner’s conclusion.

These amendments and evidence thus address most of the assertions made in support of the *Wands* analysis presented in the prior office action. The only reasoned basis for an enablement

rejection that remains relevant seems to be the statement that ‘no compounds having $R^4 = \text{aryl}$ including heteroatoms’ have been made or tested. That certainly does not establish that the claims are not enabled, though. According to MPEP 2164.02:

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

The Examiner must provide ‘adequate reasons’ to establish non-enablement: the absence of a specific example for a particular embodiment is not sufficient.

In light of the evidence and amendments presented herewith, which clarify the scope of utility and address the alleged indefiniteness of the compound description, the 35 U.S.C. § 112, first paragraph rejections are believed to be overcome. Withdrawal of these rejections in light of the declaration and amendments is therefore requested.

4. The Examiner referred to a rejection of certain claims under 35 U.S.C. § 102(a) or alternatively under 103(a) that was “maintained for reason of record”, alleging that Applicant did not respond to an outstanding rejection. The previous Office action, however, does not mention any outstanding prior art rejections; it made reference to a ‘potential’ 102(f) or 102(g) issue with respect to the CA 139 reference, but did *not* impose a rejection thereon—and the rejections stated now are not based on 102(f) or 102(g). The CA 139 reference is not prior art to the present application, as the Applicant’s previous responses have demonstrated: it cannot provide a *prima facie* case of prior invention or of derivation, so that issue is believed to be resolved.

During the telephonic interview mentioned above, this rejection was discussed with the Examiner, who could not immediately identify the basis for any outstanding art-based rejections. Since none were indicated in the previous Office action, and the present claims are believed to be free of all previously cited art, the Applicant requests that this rejection be withdrawn.

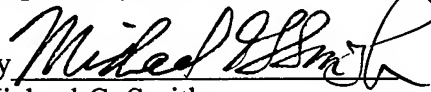
5. The Examiner referred to a rejection of claims for obviousness-type double patenting, and once again alleged that the Applicant did not respond to an outstanding rejection. No such rejection was mentioned in the previous Office action, nor can the Applicant find any unresolved issue of this nature in the preceding Office actions. During the telephonic interview, this matter was discussed with the Examiner, who suggested that this rejection likely arose due to an error by the Office. The Examiner also said that the only apparent double-patenting rejections were resolved by terminal disclaimers filed earlier and accepted by the Office. The Applicant therefore requests that this rejection be withdrawn as well.

All claims are now believed in condition for allowance. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 219002028310. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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